

## *What if I decide to drop out?*

This study is entirely voluntary. You can withdraw at any time with no penalty to you.

## *What are the benefits of Cognitive Behavioral Therapy?*

Changing your substance use requires knowing your patterns of use inside and out. We will explore these patterns as well as look at particular skills to help you change your use, such as how to cope with cravings. All information shared during treatment is confidential.

As part of your involvement in this study, you will be offered free treatment for your substance use. This treatment is called Cognitive-Behavioral Therapy (CBT). The therapy is a 1-hour session each week and includes three family sessions which we will schedule during your time in the study. CBT has been shown to help in the following areas:

- Reduce substance abuse and relapses;
- Improve family relationships;
- Enhance performance at school;
- Advance communication skills;
- Develop anger management skills; and
- Develop job-seeking skills.

## *Will I receive anything for participating?*

Yes, you will be paid for your time and travel while participating in this study.

# For More Information

For more information on the National Institute on Drug Abuse Clinical Trials Network, visit the NIDA Web site at [www.drugabuse.gov](http://www.drugabuse.gov).

For information on other clinical trials, the National Institutes of Health has created a Web site to help patients, family members, and the general public obtain information about government-sponsored clinical trials. You may log on to [www.clinicaltrials.gov](http://www.clinicaltrials.gov) to learn about ongoing or new trials of all types of health related conditions. The descriptions for individual trials include eligibility criteria, purpose of the trial, location, and how to apply if interested. The Web site is maintained and updated regularly by the National Library of Medicine.

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## National Drug Abuse Treatment Clinical Trials Network

# ADHD in Adolescent Substance Abusers

## Teenagers 13-18:

## Read About a Treatment Study Designed Just for You

## Should I Join?

## Did You Know?

You've probably heard of ADHD. You might even suffer from it. People who suffer from ADHD have a hard time paying attention. They get distracted. They procrastinate. They have a hard time getting organized and finishing work. They misplace their stuff. They may feel restless.

But did you know that teens with ADHD can also have serious problems with drugs? If you are a teen with ADHD who also uses drugs, you are more likely than other teens who use drugs to drop out of school, get into trouble, and have a harder time kicking your drug habit.

Why is this? One reason may be that many teens in drug programs don't get medication for their ADHD while they are in treatment.

The purpose of this study is to find out if Osmotic-Release Methylphenidate (OROS-MPH), a medication approved for the treatment of ADHD, compared to placebo (sugar pill), can help teenagers with drug or alcohol problems.

## Who Can Be In The Study?

You can be in this study if you:

- Are 13-18 years old;
- Have ADHD and are willing to take medication or placebo (sugar pill) for it;
- Have a drug or alcohol problem; and
- Are willing to participate in the Cognitive Behavioral Therapy (CBT) used in this study to help you stop using alcohol or drugs.

## What If I Want To Be In The Study?

**1.** You (and your parent/guardian if you are under 18) will contact the research clinic for a confidential telephone screening to see if you might be able to participate.

**2.** If you qualify based on this screening, you (and parent/guardian if applicable) will come in for an appointment at the clinic. At this visit, the study will be explained to you in detail and you will be asked in private about your drug/alcohol use and your medical history, including ADHD.

**3.** If you still qualify, you will have a physical exam and blood test to make sure you are healthy (and a pregnancy test if female), a urine test for drugs, and an ECG to check your heart. You will answer more questions (in private) about your drug use and ADHD.

**4.** If you meet the criteria, you will be assigned at random (for example, by the flip of a coin) to receive OROS-MPH or placebo. You will be asked to take the OROS-MPH or placebo every day for 16 weeks.

**5.** You will come to the clinic every week for about 2 hours to:

- Participate in 1-hour CBT sessions;
- Answer questions about your drug use and ADHD;
- Give a urine sample to test for drugs of abuse; and
- Meet with a clinician to be sure you are not having any bad reactions to the study medications.

**6.** At the end of 16-weeks, you will again have a small amount of blood taken.

**7.** You will come back for a follow-up visit 1 month after your last study visit. In total, you will be in the study for about 5 months.

## Questions

### ***Does the medication have any side effects?***

The medication in this study may cause side effects and may react with other medications or drugs you might be taking. You will be given a form that lists the possible side effects for the medications you will take.

While you are in the study, you will be watched for possible side effects. Still, some side effects may be harmful and some may be unknown. Ask the clinician before taking any other medication or drug.

### ***Is the information I provide private?***

There is a small risk that others who are not involved in the study will see the information you give us. However, the investigators and their staffs are well trained in keeping your information confidential. You will also be given an ID number that will be used on all forms instead of your name. In addition, all information collected from the participants is kept in locked areas in the clinic.